

Dräger Medical, Inc.



Operator's Instruction Manual

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Air-Only Mode for the Narkomed 6000 Anesthesia System

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1

Introduction

This section introduces you to the Air-Only Mode Operator's Manual and provides important safety information.

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Operator's Responsibility for Patient Safety

Draeger Medical anesthesia products are designed to provide the greatest degree of patient safety that is practically and technologically feasible. The design of the equipment, the accompanying literature, and the labeling on the equipment take into consideration that the purchase and use of the equipment are restricted to trained professionals, and that certain inherent characteristics of the equipment are known to the trained operator. Instructions, warnings, and caution statements are limited, therefore, to the specifics of the Draeger Medical design. This publication excludes references to hazards that are obvious to a medical professional, to the consequences of product misuse, and to potentially adverse effects in patients with abnormal conditions. Product modification or misuse can be dangerous. Draeger Medical disclaims all liability for the consequences of product alterations or modifications, as well as for the consequences that might result from the combination of Draeger Medical products with products supplied by other manufacturers if such a combination is not endorsed by Draeger Medical.

The operator of the anesthesia system must recognize that the means of monitoring and discovering hazardous conditions are specific to the composition of the system and the various components of the system. It is the operator, and not the various manufacturers or suppliers of components, who has control over the final composition and arrangement of the anesthesia system used in the clinical practice. Therefore, the responsibility for choosing the appropriate safety monitoring devices rests with the operator and user of the equipment.

Patient safety may be achieved through a variety of different means depending on the institutional procedures, the preference of the operator, and the application of the system. These means range from electronic surveillance of equipment performance and patient condition to simple, direct contact between operator and patient (direct observation of clinical signs). The responsibility for the selection of the best level of patient monitoring belongs solely to the equipment operator. To this extent, the manufacturer, Draeger Medical, disclaims responsibility for the adequacy of the monitoring package selected for use with the anesthesia system. However, Draeger Medical is available for consultation to discuss monitoring options for different applications.

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Furthermore, buyer acknowledges that the consideration for the products, equipment, and parts sold reflects the allocation of risk and the limitations of liability referenced herein.

Restriction

Federal law restricts this device to sale by, or on the order of, a physician.

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Disclaimer

The content of this manual is furnished for informational use only and is subject to change without notice. Draeger Medical, Inc. assumes no responsibility or liability for any errors or inaccuracies that may appear in this manual.

Recommendations

In the interest of patient safety, Draeger Medical strongly advocates the use of an oxygen analyzer, pressure monitor, a volume monitor, and an end-tidal CO₂ monitor in the breathing circuit at all times.

Purpose of This Manual

This manual provides operating instructions for Air-Only Mode. It is intended for use by trained clinical professionals familiar with accepted medical procedures, practices, and terminology used in delivery of anesthesia and patient monitoring.

How This Manual Is Organized

All users of the Air-Only Mode must read this manual completely before using the equipment. This manual is intended to be used in conjunction with the *Narkomed 6000 Anesthesia System Operator's Instruction Manual*.

In addition to this introductory section, this manual contains three other sections:

Section 2 - "General Description" provides a summary of Air-Only Mode features and functions.

Section 3 - "Preuse Checkout" provides a checkout procedure for Air-Only Mode.

Section 4 - "Air-Only Mode Operation" contains detailed operational information for Air-Only Mode.

Conventions Used in This Manual

This manual has several conventions to help organize the information presented. Please read about these conventions carefully to understand their significance in the manual.

Typefaces

Different typefaces are used throughout the manual to differentiate between narrative information and machine messages and labels.

Warnings and Cautions

Parts of this manual may contain warning and caution statements about Air-Only Mode.

- *Warning* statements give important information that, if ignored, could lead directly to a patient's or operator's injury.
- *Caution* statements give important information that, if ignored, could lead directly to equipment damage and, indirectly, to a patient's injury.

General Warnings and Cautions

The following list of warnings and cautions apply to general operation of the Air-Only Mode. Warnings and cautions about specific functions appear with those topics.

WARNING: Any person involved with the operation of Air-Only Mode must be thoroughly familiar with this instruction manual. However, instructions in this manual in no way supersede established medical procedures for patient care.

WARNING: The Air-Only Mode is designed to be operated under the constant surveillance of a qualified operator.

WARNING: To ensure patient safety:

- This device should be used by, or on the order of, a physician.
- Constant attention by a qualified professional is needed whenever a patient is under anesthesia or connected to a ventilator. Some equipment malfunctions may pass unnoticed in spite of the monitor alarm.
- Always make sure that alarm limits are set and alarms are active when monitoring a patient. Do not rely exclusively on the audible alarm system for patient monitoring. Adjusting the alarm volume to a low level during patient monitoring can jeopardize the patient.
- If the accuracy of any value display is in doubt, first determine the patient's vital signs by alternate means before verifying that the Air-Only Mode is working correctly.
- If the display loses patient data, it is possible that active monitoring is not being performed. Close patient observation or alternate monitoring devices should be used until monitor function is restored.
- The Air-Only Mode bypasses conventional minimum O₂ controls, allowing the clinician to deliver only air with no oxygen flow. Constant surveillance of the patient's inspired oxygen level while in Air-Only Mode should be provided.

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General Description

This section describes Air-Only Mode Option features and general functionality.

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Air-Only Mode Overview

The Air-Only Mode allows the clinician to deliver 21% oxygen (air) as the fresh gas. The clinician selects this mode using a control button located on the standard Narkomed 6000 screen.

WARNING: Minimum oxygen flow is disabled in Air-Only Mode.

Air-Only Mode Control Button

The Air-Only Mode button is located on the secondary taskbar at the bottom of the main Narkomed 6000 screen. This button allows the clinician to toggle between Air-Only Mode and normal N₂O/Air/O₂ operating mode.

Note: This control button is displayed only if the Air-Only Mode option is installed on the machine; if the option is not installed, the key is not displayed.

Note: The label on the button always reflects the action that the clinician can select if the button is touched, *not* the current status.

Figure 2-1. Secondary Taskbar Showing the Air-Only Mode Control Button

		Air-Only Mode	Vent Info	Low Flow Wizard	Limits Autoset	Utilities	Auto Pressure Thrshld	O2 Cal	Alarm Suspend	Main Screen	To Primary Keys
--	--	---------------	-----------	-----------------	----------------	-----------	-----------------------	--------	---------------	-------------	-----------------

Figure 2-2. Secondary Taskbar Showing the N2O/Air/O2 Control Button

		N2O/Air O2	Vent Info	Low Flow Wizard	Limits Autoset	Utilities	Auto Pressure Thrshld	O2 Cal	Alarm Suspend	Main Screen	To Primary Keys
--	--	------------	-----------	-----------------	----------------	-----------	-----------------------	--------	---------------	-------------	-----------------

Air-Only Mode Status Message

If the Air-Only Mode option is installed, a message indicating the status of the option is displayed in the oxygen parameter box.

When Air-Only Mode is *enabled*, the message Air-Only Mode is displayed below the oxygen concentration value (See [Figure 2-3](#).) This indicates that minimum oxygen flow has been turned off, allowing the clinician to use air only to achieve 21% oxygen. Oxygen and nitrous oxide flows must be turned off for proper operation.

Figure 2-3. Air-Only Mode Message in Oxygen Parameter Box



When Air-Only Mode is *disabled*, the message N2O/Air/O2 is displayed below the oxygen concentration value (See [Figure 2-4](#).) This indicates that minimum oxygen flow is on and all three fresh gases will function normally.

Figure 2-4. N2O/Air/O2 Message in Oxygen Parameter Box



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Preuse Checkout

This section contains a preuse checkout procedure for Air-Only Mode.

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Preuse Checkout for Air-Only Mode

Use this procedure daily and between successive cases to verify proper operation of Air-Only Mode. This checkout procedure should be used as part of the comprehensive checkout procedure provided in the *Narkomed 6000 Operator's Instruction Manual*.

1. Enable Air-Only Mode by pressing the **[Air-Only Mode]** control button and then pressing the **[Continue]** button in the dialog box.
2. Turn all flow control knobs completely off and verify that no fresh gas (including oxygen) is flowing through any flow tube.
3. Verify that the message Air-Only Mode is displayed at the bottom of the oxygen parameter box.
4. Turn up the air flow control and verify that flow of air is possible with no oxygen flowing.
5. Turn off the air flow control.
6. If Air-Only Mode will not be used in the next case, return to N₂O/Air/O₂ operation by pressing the **[N2O/Air/O2]** control button and then pressing the **[Continue]** button in the dialog box.

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Air-Only Mode Operation

This section contains operational information for Air-Only Mode.

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Enabling Air-Only Mode

Air-Only Mode can be enabled only when there is valid oxygen data and when the oxygen sensor is properly calibrated.

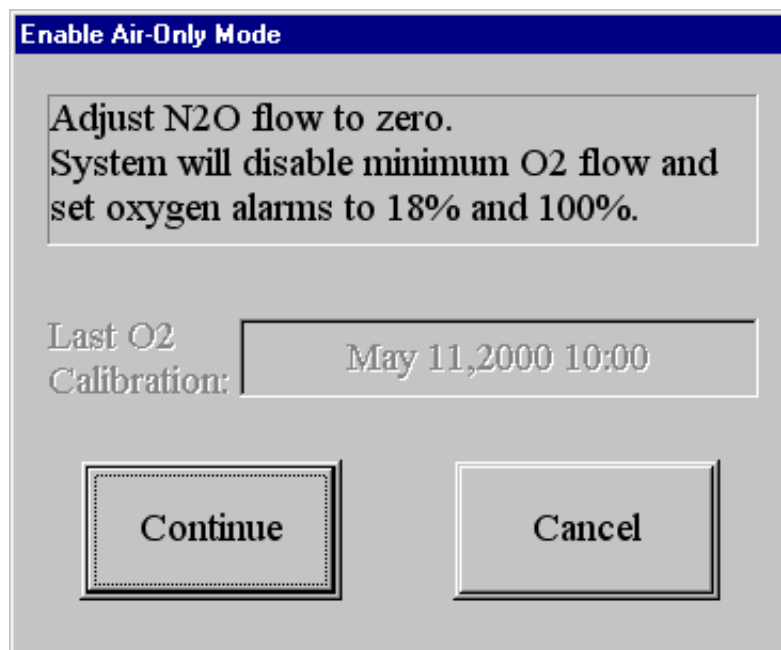
If the **[Air-Only Mode]** button is touched when there is no valid oxygen reading, the hint message “A valid oxygen concentration must be displayed to select Air-Only Mode” is displayed above the control button.

If the **[Air-Only Mode]** button is touched while there is an O2 CAL DUE alarm posted, the hint message “O2 must be calibrated to select Air-Only Mode” is displayed above the control button.

To enable Air-Only Mode:

1. Press **[To Secondary Keys]** on the main screen taskbar.
Several control buttons change to choose additional tasks.
2. Press **[Air-Only Mode]** on the secondary taskbar. If there is valid oxygen data and no O2 CAL DUE alarm is posted, the following dialog box is displayed:

Figure 4-1. Enable Air-Only Mode Confirmation Dialog Box



WARNING: If the N₂O flow control valve is open while in Air-Only Mode, it is possible that N₂O will be delivered. Close the N₂O flow control valve to avoid inadvertent delivery of N₂O to the patient. Also adjust the oxygen flow control valve to an appropriate level.

- to cancel the request, touch **[Cancel]**.
 - to enable Air-Only Mode, adjust N₂O flow to zero, appropriately adjust oxygen flow, and touch **[Continue]**. The following actions occur:
 - the minimum oxygen flow is disabled
 - the label of the control button on the secondary taskbar changes to N₂O/Air/O₂
 - the message Air-Only Mode is displayed under the oxygen concentration value in the oxygen parameter box
 - the oxygen low alarm limit is set to 18%
 - the oxygen high alarm limit is set to 100%
3. Set air flow to the desired level.

Special Conditions in Air-Only Mode

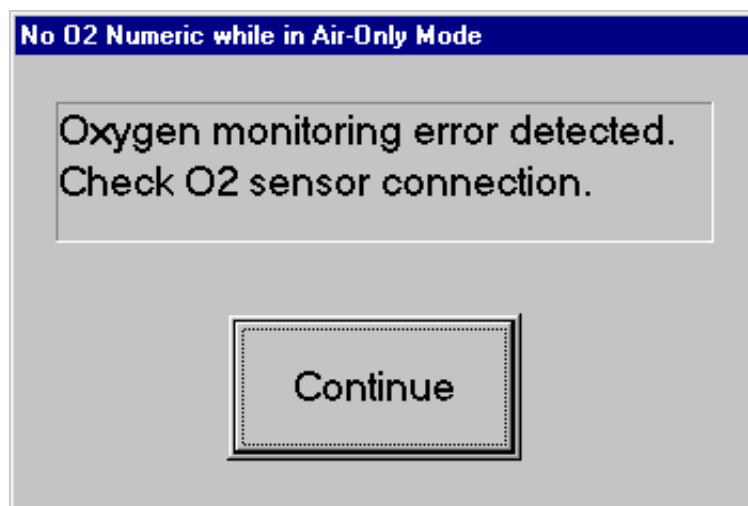
The following paragraphs describe the dialog boxes that are displayed during specific conditions that can occur in Air-Only Mode.

Loss of O₂ Numeric Data in Air-Only Mode

Dialog boxes informing the clinician of loss of numeric data may appear on the screen while in Air-Only Mode.

If the loss of numeric data is due to an oxygen sensor disconnect alarm (O₂ SENSOR DISC), the following dialog box appears on the screen:

Figure 4-2. Loss of Numeric Data in Air-Only Mode (Sensor Disconnect)



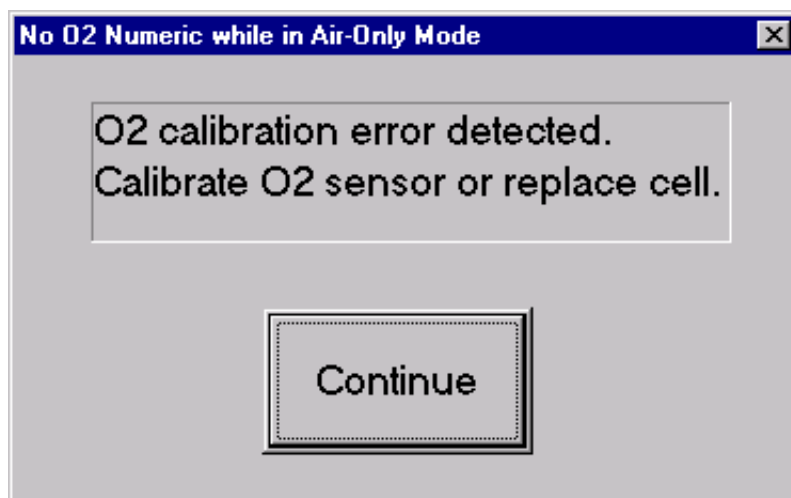
- Ensure that the oxygen sensor cable at the breathing system interface panel is properly connected.
- Touch **[Continue]** to remove this dialog box. The system remains in Air-Only Mode.

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Air-Only Mode Operation

If the loss of numeric data is due to a CAL O2 SENSOR or an O2 CAL ERROR alarm, the following dialog box appears on the screen:

Figure 4-3. Loss of Numeric Data in Air-Only Mode (Calibration Problem)

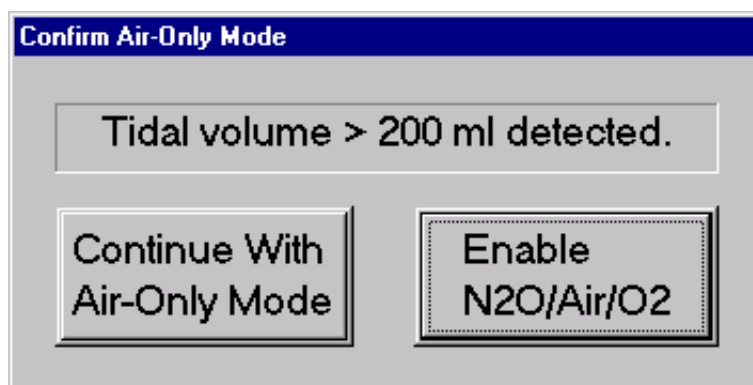


- Calibrate the oxygen sensor or replace the oxygen sensor capsule. Refer to the *Narkomed 6000 Anesthesia System Operator's Instruction Manual* for specific instructions.
- Touch **[Continue]** to remove this dialog box. The system remains in Air-Only Mode.

Adult Tidal Volumes Detected in Air-Only Mode

The following dialog box appears on the screen if a tidal volume greater than 200 ml is detected for three consecutive breaths while in Air-Only Mode and while in an automatic ventilation mode:

Figure 4-4. Adult Tidal Volumes Detected

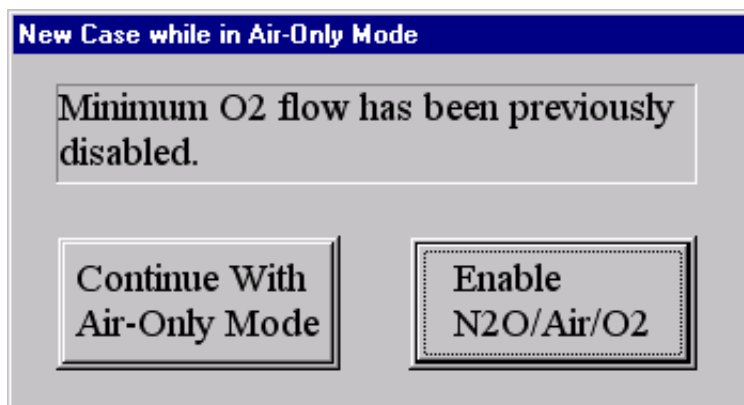


- To continue, touch **[Continue With Air-Only Mode]**. The dialog box is removed and the system remains in Air-Only Mode.
- To switch to N₂O/Air/O₂ operation (so that all three gases can be delivered), touch **[Enable N₂O/Air/O₂]**.

New Case in Air-Only Mode

The following dialog box appears on the screen if the **[New Case]** control button is touched while in Air-Only Mode:

Figure 4-5. New Case in Air-Only Mode



- To continue, touch **[Continue With Air-Only Mode]**. The dialog box is removed and the system remains in Air-Only Mode.
- To switch to N₂O/Air/O₂ operation (so that all three gases can be delivered), touch **[Enable N₂O/Air/O₂]**.

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Air-Only Mode Operation

VPO Hardware Fault in Air-Only Mode

The dialog box shown in [Figure 4-6](#) appears on the screen if communication with the volume/pressure/oxygen (VPO) monitor on the Narkomed 6000 is lost while in Air-Only Mode.

This dialog indicates that a hardware fault has occurred and the Narkomed 6000 system monitor is unable to determine whether the minimum oxygen flow delivery is truly off.

WARNING: Oxygen concentration levels can rise if control of minimum oxygen flow delivery is lost.

Figure 4-6. VPO Hardware Fault in Air-Only Mode



- Take appropriate measures to ensure patient safety.
- Touch **[Continue]** to remove this dialog box.

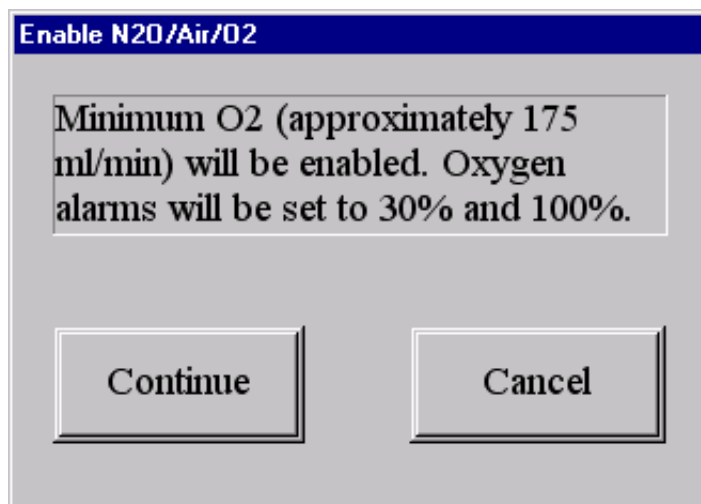
Enabling N₂O/Air/O₂ Operation

To exit Air-Only Mode and enable N₂O/Air/O₂ operation:

1. Press **[To Secondary Keys]** on the main screen taskbar.
Several control buttons change to choose additional tasks.
2. Press **[N2O/Air/O2]** on the secondary taskbar. The following dialog box is displayed:

NOTE: N₂O/Air/O₂ operation can also be enabled immediately by touching the **[Enable N2O/Air/O2]** button in certain dialog boxes that appear while in Air-Only Mode. See [“Special Conditions in Air-Only Mode”](#) on page 4-3.

Figure 4-7. Enable N2O/Air/O2 Confirmation Dialog Box



- to cancel the request, touch **[Cancel]**.
- to enable N₂O/Air/O₂ operation, touch **[Continue]**. The following actions occur:
 - the minimum oxygen flow is enabled
 - the label of the control button on the secondary taskbar changes to Air-Only Mode
 - the message N2O/Air/O2 is displayed under the oxygen concentration value in the oxygen parameter box
 - the oxygen low alarm limit is set to 30%
 - the oxygen high alarm limit is set to 100%

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